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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 6,441,145

mailed  
OCT 4 2012  
by PLA

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,441,145, claims of which cover the human biological product ATryn® (Antithrombin (Recombinant)) and methods of producing the human biological product ATryn® (Antithrombin (Recombinant)), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,270 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,270 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 21, 2011 (76 Fed. Reg. 15323). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\ &= 4,468 - 2,112 - 0 - \frac{1}{2} (4,285 - 2,112) \\ &= 1,270 \text{ days (3.5 years)}\end{aligned}$$

Since the regulatory review period began November 14, 1996, before the patent issued (August 27, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 14, 1996, to and including August 27, 2002, is 2,112 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the

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<sup>1</sup> Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of  $\frac{1}{2} (\text{TP} - \text{PGTP})$ .

period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,441,145
Granted:	August 27, 2002
Original Expiration Date <sup>2</sup> :	February 21, 2015
Applicant:	Paul DiTullio et al.
Owner of Record:	GTC Biotherapeutics, Inc.
Title:	Transgenically Produced Antithrombin III
Product Trade Name:	ATryn® (Antithrombin (Recombinant))
Term Extended:	1,270 days
Expiration Date of Extension:	August 14, 2018

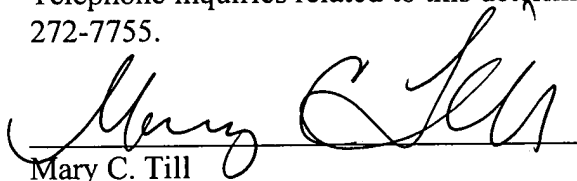
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<sup>2</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail:      Mail Stop Hatch-Waxman PTE      By FAX:      (571) 273-7755  
                 Commissioner for Patents  
                 P.O. Box 1450  
                 Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc:      Office of Regulatory Policy  
         Food and Drug Administration  
         10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
         Silver Spring, MD 20993-0002

RE: ATryn® (Antithrombin  
(Recombinant))  
Docket No.: FDA-2009-E-0241

Attention: Beverly Friedman